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November 20, 2000

Mr. William K. Hubbard
Sr. Assoc. Commissioner for Policy, Planning, and Legislation
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

'00 NOV 20 P1:18

RE: Comments with respect to Docket # 92N-0297

Dear Mr. Hubbard:

On behalf of Premier Purchasing Partners, LP (PPLP), the group purchasing subsidiary of Premier, Inc., I respectfully take this opportunity to submit comments with respect to FDA Hearing Docket # 92N-0297.

Premier, Inc. is the parent company of a strategic alliance of leading not-for-profit hospital and healthcare systems in the United States. Aggregately, Premier's more than 200 owner-systems operate or are affiliated with more than 1,800 hospital facilities across the nation. Headquartered in San Diego, CA, with facilities in Charlotte, NC, Chicago, IL and Washington, DC, the Premier family of companies provides an array of resources in support of healthcare delivery, including performance improvement, clinical technology, practice management, and federal advocacy services.

Premier Purchasing Partners, LP is a group purchasing subsidiary representing approximately 30 percent of U.S. healthcare entities. PPLP negotiates product and distribution agreements on behalf of its members. In this capacity, Premier staff is often involved in assisting members obtain products in short supply, such as IGIV and flu vaccine.

The attached comments have been prepared primarily by Allen Dunehew, senior director of managed care pharmacy for the Premier Pharmacy business unit. The document reflects the experiences of PPLP and its members, particularly in dealing with the multitude of distributors in those situations.

Establishing the requirement for a "drug pedigree" may or may not be the solution. However, the nation's recent experiences with the manufacture and distribution of the flu vaccine, and the 300 to 500 percent profit some distributors have collected demonstrate that swift action is needed—particularly in light of the potential negative impact on patient care.

For clarification or additional information, contact Allen Dunehew at 630.891.4502, or Bert Patterson, vice president of Pharmacy, at 630.891.4533.

Again, we appreciate the opportunity to submit comments on this matter.

Sincerely,

Herb Kuhn
Vice President
Premier Advocacy

92N-0297

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Responses to specific questions outlined by the FDA in Section II. Scope of the Hearing:

A1. The proposed requirements may, in fact, limit the ability of unauthorized distributors to engage in drug distribution. However, for the reasons cited below, this may actually be a positive step for patient care. The specific limitations would likely be due to the lack of information systems of an UA to track product lot # and acquisition source information to the specific and individual package unit. The distributor group might argue that this level of detail is not available. However, this obstacle can partially be resolved by also making the requirement to disclose this information the responsibility of the seller as well as the purchaser. This requirement would, however, add a new level of product tracking that is not currently available. Today, most distributors can track product by lot # but do not have the capability to differentially track 40,000 vials within a lot to the specific package.
A2. This legislation may have little impact on the access to products even if some of the UA exited the market. In fact, it might actually increase availability during periods of product shortages if this were to occur because of a reduced number of distributors that are trying to stock the market. It might also decrease the incidence of exorbitant markups that some UA take when there is a shortage of a product.
A3. There would be no greater risk than there currently is today. A "drug pedigree" would significantly decrease the inappropriate distribution of products. There currently is no mechanism today to ensure that inappropriate distribution of a product is not occurring.
A4. The primary additional cost or burden would most likely be due to increased costs associated with information and process systems that have the ability to track product movement to the individual package from receipt to delivery at the point of sale.
A5. A standard format would be advisable to ensure that the minimum set of information is communicated.
A6. Using sales by a manufacturer to a distributor as the criteria for defining an authorized distributor would likely increase the number of authorized distributors. This designation is usually a business designation and the definition probably varies according to the business practices of the manufacturer.

B1. Distributors of blood derived products are similar to those for pharmaceutical products with the exception that there are probably more of the specialty type of distributors in the blood derived products that in pharmaceuticals because of the consistent issue of adequate supply for the blood derived products. Many of the blood derived product distributors have not expanded into general pharmaceutical distribution particularly for products in short supply due, in part, to the significant profit potential in that area.
B2. The effect would be similar to the distributor issues identified in Section A above. There likely would be little negative effect on patient care and perhaps some potential for improvement because a small amount of product that is in short supply would be dispersed among fewer distributors and would be sold directly to the patient or provider rather than to other distributors before it ultimately reaches the patient.
B3. There could be an increased risk of inappropriate distribution if health care entities (HCEs) are exempted from the final rules. HCEs are in the business of caring for patients and not acting as distributors. In addition, much of this type of supply would be purchased by HCEs under preferential pricing which is usually restricted from resale. Administration or distribution directly to a patient would not violate restriction.
B4. Yes, in most cases, these products are distributed under contract at preferential prices to the HCEs, usually with the restriction that these products may not be resold.

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The following are general comments on the subject.

- In times of shortage or for products that historically are in short supply, placing product into stock at the multitude of secondary distributors creates an additional strain on the supply chain and often results in supplies not being available in the most appropriate market and/or a pricing scenario where some distributors/wholesalers take advantage of the supply issues by placing exorbitant markups on these products (e.g. flu vaccine, IGIV, Prolastin, and some factor products).
- The above can create a situation that adversely affects patient care due to lack of availability and/or exorbitant prices (same examples as above)
- Since many of the products that find their way into this market are biologicals and require refrigeration, there is no way to be sure that the product has been stored in compliance with USP/FDA standards, The comments in the hearing notice indicated that this was a significant issue for the smaller distributors. It does however have the potential to become a serious patient care issue. As a minimum, the secondary suppliers should be required to certify as to the integrity of the storage of the products under their control and that they have taken such steps as necessary to verify that the supplier of the product to them has taken the appropriate steps.
- Any type of requirement for a "pedigree" would probably only be effective if the requirement was placed upon the wholesaler/distributor selling the product rather than on the buyer.
- In response to the comment regarding the phase-in issues, the regulations could be stated such that they are only in effect for product that is sold by the original source after the effective date of the regulations.
- In some cases, the supply of products in this secondary distribution market is obtained from other "non-traditional" distribution sites. Originally, some of this product may have been purchased from health care entities that received the product under preferential prices, which in some cases may be considered diversion.